K030235

APR 2 3 2003

510(K) SUMMARY

Date: 21 January 2003

Submission Correspondent: Emergo Group, Inc.

Address: 1684 East Gude Drive, Suite 202
Rockville, MD 20850

Phone: (301) 762-2828
Fax: (301) 762-4043

Contact: Mr. Rene van de Zande

Trade Name: F1 Diode Laser System
Common Name: Pulsed Diode Laser
Classification: Laser Instrument, Surgical, Powered: GEX

Description: The F1 Diode Laser System delivers a pulsed infrared laser light at a wavelength of 810 nanometers. The laser consists of several interconnected sections: The cabinet which houses the laser diode, the power supply, the PC-104, and the microcontroller, the umbilical which houses the fiber optics delivery system, and the handpiece and the external TE chiller.

Intended Use: The Device is indicated for hair removal and permanent hair reduction in dermatology and plastic surgery procedures.

Predicate Devices: The predicate devices referenced in this submission are: the Opus Medical F1 Diode Laser System for the existing indication, the Lumenis LightSheer™ Pulsed Diode Array Laser System, Iridex Iriderm Apex 800, and the Altus Medical Modified CoolGlide Aesthetic Lasers.

Summary and Conclusions Regarding Substantial Equivalence:
By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

The differences between theF1 Diode Laser System and the predicate devices cited do not raise any different questions regarding safety and effectiveness. The differences in the technological characteristics are minimal. Furthermore, the subject of this submission is identical to the previously cleared F1 Diode Laser System with the exception of the indications for use. The new indications are nearly identical to the indications of two of the predicate devices.

The device, as designed, is as safe and effective as the predicate devices, and the device is substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2003

Opus Medical, Inc.
c/o Ms. Rene van de Zande
President
Emergo Group, Inc.
1684 East Gude Drive, Suite 202
Rockville, Maryland 20850

Re: K030235
Trade/Device Name: F1 Diode Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 22, 2003
Received: January 23, 2003

Dear Ms. van de Zande:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030235

Device Name: **F1 Diode Laser System**

Indications for Use:

The Device is indicated for hair removal and permanent hair reduction in dermatology and plastic surgery procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030235

(Optional Format 3-10-98)

(Posted July 1, 1998)